November 2003

Proposed re-write – Code Chapter on Bovine Spongiform Encephalopathy:

We continue to support the OIE's efforts to streamline and clarify the BSE Code Chapter. In the attached document, we recommend reducing the existing categories for classifying a country with respect to BSE from five to three categories, and suggest defining these categories as BSE negligible risk, BSE minimal risk, and BSE risk. The health conditions for the movement of live animals and their products from each of these categories would be commensurate with the risk presented by that country or zone.

In addition to our recommendation to reduce the number of categories, we are also recommending a reduction in the required time frames for certain actions. The existing Code Chapter lists specific time frames for certain actions in *Articles 2.3.13.2 – 7*. In some instances, this time frame is 7 years (for example, surveillance should have been conducted for at least 7 years) while the references to a feed ban generally specifies 8 years. These time frames can be somewhat arbitrary and limiting. Therefore, we suggest that either the time frames be decreased to 5 years, or that some flexibility be written into these guidelines. For example, in certain instances, a combination of risk management factors may lead to the same risk determination, but a specific requirement (such as a feed ban for 8 years) may not be strictly complied with. Allowing some flexibility would address this type of situation.

We hope that the members of the Code Commission will find our recommendations useful and look forward to continued close collaboration on this and other subjects.

CHAPTER 2.3.13.

BOVINE SPONGIFORM ENCEPHALOPATHY

Article 2.3.13.1.

The recommendations in this Chapter are intended to manage the human and animal health risks associated with the presence of the bovine spongiform encephalopathy (BSE) agent in cattle (*Bos taurus* and *B. indicus*) only.

Article 2.3.13.2.

The BSE status of the cattle population of a country or zone can only be determined on the basis of the following criteria:

1) the outcome of a risk assessment identifying all potential factors for BSE occurrence and their historic perspective, in particular:

   a) the potential for introduction and recycling of the BSE agent through consumption by cattle of *meat-and-bone meal* or *greaves* of ruminant origin;

   b) importation of *meat-and-bone meal* or *greaves* potentially contaminated with BSE or feedstuffs containing either;

   c) importation of animals or embryos/oocytes (other than cattle embryos described in Article 2.3.13.8.) potentially infected with BSE;

   d) epidemiological situation concerning all animal TSE in the country or zone;

   e) extent of knowledge of the population structure of cattle, sheep and goats in the country or zone;

   f) the origin and use of ruminant carcasses (including fallen stock), by-products and slaughterhouse waste, the parameters of the rendering processes and the methods of animal feed manufacture;

2) on-going awareness programme for veterinarians, farmers, and workers

involved in transportation, marketing and slaughter of cattle to encourage reporting of all cases of neurological disease in adult cattle;

3) compulsory notification and investigation of all cattle showing clinical signs compatible with BSE;

4) a BSE surveillance and monitoring system with emphasis on risks identified in point 1) above, taking into account the guidelines in Appendix 3.8.4.; records of the number and results of investigations should be maintained for at least 7 years;

5) examination in an approved laboratory of brain or other tissues collected within the framework of the aforementioned surveillance system.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

Article 2.3.13.3.

BSE negligible risk country or zone

The cattle population of a country or zone may be considered to have a BSE negligible risk if the following conditions can be met:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

2) either:

   a) there has been no *case* of BSE in native born cattle during the previous 5 years; and either:

      i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 5 years; or

      ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 5 years and it has been demonstrated that for at least 5 years no ruminant-origin *meat-and-bone meal* or *greaves* have been fed to ruminants;

   OR

   b) all *cases* of BSE have been clearly demonstrated to originate directly

from the importation of live cattle, and the affected cattle have been slaughtered and completely destroyed; and either:

i) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 5 years; or

ii) the criteria in point 3) of Article 2.3.13.2. have been complied with for at least 5 years and it has been demonstrated that for at least 5 years no ruminant-origin *meat-and-bone meal* or *greaves* have been fed to ruminants;

Article 2.3.13.4.

BSE minimal risk country or zone

The cattle population of a country or zone may be considered as presenting a minimal BSE risk should the country or zone comply with the following requirements:

1) a risk assessment, as described in point 1) of Article 2.3.13.2., has been conducted and it has been demonstrated that appropriate measures have been taken for the relevant period of time to manage any risk identified;

b) the BSE incidence rate, calculated on the basis of indigenous *cases*, has been less than one case per million during each of the last four consecutive 12-month periods within the cattle population over 24 months of age in the country or zone *(Note: For countries with a population of less than one million adult cattle, the maximum allowed incidence should be expressed in cattle-years.)*, and:

i) the ban on feeding ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced for at least 5 years;

ii) the criteria in points 2) to 5) of Article 2.3.13.2. have been complied with for at least 5 years;

iii) the affected cattle were completely destroyed:

Article 2.3.13.5.

BSE risk country or zone

The cattle population of a country or zone may be considered as presenting a BSE risk if neither the conditions in Article 2.3.13.3 nor Article 2.3.13.4 can be met.

Article 2.3.13.6.

Regardless of the BSE status of the *exporting country*, *Veterinary Administrations* should authorise without restriction the import or transit through their territory of the following *commodities*:

1) *milk* and *milk products*;

2) semen and *in vivo* derived cattle embryos collected and handled in accordance with the recommendations of the International Embryo Transfer Society;

3) protein-free tallow (maximum level of insoluble impurities of 0.15% in weight) and derivatives made from this tallow;

4) dicalcium phosphate (with no trace of protein or fat);

5) hides and skins;

6) gelatin and collagen prepared exclusively from hides and skins.

Article 2.3.13.7.

When importing from a BSE negligble risk country or zone, *Veterinary Administrations* should require:

<u>for all *commodities* from cattle not listed in Article 2.3.13.6.</u>

the presentation of an *international veterinary certificate* attesting that the country or zone complies with the conditions in Article 2.3.13.3. to be considered to have a negligible BSE risk.

Article 2.3.13.8.

When importing from a BSE minimal risk country or zone, *Veterinary Administrations* should require:

for cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as presenting a minimal BSE risk;

2) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

3) cattle selected for export:

   a) are identified by a permanent identification system enabling them to be traced back to the dam and herd of origin and are not the progeny of BSE suspect or confirmed females;

   b) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced.

Article 2.3.13.9.

When importing from a BSE minimal risk country or zone, *Veterinary Administrations* should require:

for *fresh meat* (bone-in or deboned) and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.4. to be considered as presenting a minimal BSE risk;

2) ante-mortem inspection is carried out on all cattle from which the meat or *meat products* destined for export originate;

3) cattle from which the meat or *meat products* destined for export originate were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process (laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity);

4) the *fresh meat* and *meat products* destined for export do not contain skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older and the distal ileum of cattle of any age.

Article 2.3.13.10.

When importing from a country or zone with a BSE risk, *Veterinary Administrations* should require:

for *fresh meat* and *meat products* from cattle

the presentation of an *international veterinary certificate* attesting that:

1) the country or zone complies with the conditions in Article 2.3.13.5. to be considered as presenting a BSE risk;

2) the meat or meat products destined for export do not contain skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, dorsal root ganglia, or vertebral column of cattle aged 6 months or older and the distal ileum of cattle of any age, all of which have been removed in a hygienic manner;

3) the meat destined for export, if obtained from animals over 9 months of age, has been deboned and does not contain nervous and lymphatic tissues exposed during a deboning process, all of which have been removed in a hygienic manner;

4) the *meat products* destined for export are derived from deboned meat and do not contain the tissues listed in point 2 of this Article nor nervous and lymphatic tissues exposed during a deboning process, nor mechanically separated meat from skull and vertebral column of bovine animals, all of which have been removed in a hygienic manner;

5) a system is in operation enabling the *fresh meat* and *meat products* destined for export to be traced back to the *establishments* from which they are derived;

6) ante-mortem inspection is carried out on all bovines;

7) the cattle from which the *meat* or *meat products* destined for export originate:

   a) were identified by a permanent identification system enabling them to be traced back to the dam and herd of origin;

b) are not the progeny of BSE suspect or confirmed females; and either:

i) were born after the date from which the ban on the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been effectively enforced; or

ii) were born, raised and had remained in herds in which no *case* of BSE had been confirmed for at least 7 years;

c) were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity or to a pithing process;

8) the feeding of ruminants with *meat-and-bone meal* and *greaves* derived from ruminants has been banned and the ban has been effectively enforced;

9) affected cattle if alive in the country or zone, when slaughtered or at death, are completely destroyed.

Article 2.3.13.11.

Ruminant-derived *meat-and-bone meal* or *greaves*, or any commodities containing such products, which originate from countries with a BSE minimal risk or BSE risk should not be traded between countries.

Article 2.3.13.12.

Live cattle which originate from countries with a BSE risk should not be traded between countries.

Article 2.3.13.13.

1) From cattle originating from a country or zone with a BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices: skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord, dorsal root ganglia, or vertebral column of cattle aged 6 months or older and the distal ileum of cattle of any age. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

2) From cattle, originating from a country or zone with a minimal BSE risk, the following commodities, and any commodity contaminated by them, should not be traded for the preparation of food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices skull, brain, trigeminal ganglia, eyes, tonsils, spinal cord and dorsal root ganglia of cattle aged 30 months or older and the distal ileum of cattle of any age. Food, feed, fertilisers, cosmetics, pharmaceuticals or medical devices prepared using these commodities should also not be traded.

Article 2.3.13.14.

Veterinary Administrations of *importing countries* should require:

<u>for gelatin and collagen prepared from bones and intended for food or feed, cosmetics, pharmaceuticals including biologicals, or medical devices</u>

the presentation of an *international veterinary certificate* attesting that the bones came from:

1) a BSE negligible or BSE minimal risk country or zone; or

2) a country or zone with a BSE risk; and

   a) skulls and vertebrae (excluding tail vertebrae) have been excluded;

   b) the bones have been subjected to a process which includes all the following steps:

      i) pressure washing (degreasing),

      ii) acid demineralization,

      iii) prolonged alkaline treatment,

      iv) filtration,

      v) sterilisation at <u>≥</u>138°C for a minimum of 4 seconds,

      or to an equivalent process in terms of infectivity reduction.

Article 2.3.13.15.

Veterinary Administrations of *importing countries* should require:
for tallow (other than protein-free tallow as defined in Article 2.3.13.6.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that it originates from:

1) a BSE negligible risk country or zone, or

2) a country or zone with a minimal BSE risk, and it originates from cattle which have been subjected to ante-mortem inspection with favourable results and has not been prepared using the tissues listed in point 4 of Article 2.3.13.10., or

3) a country or zone with a BSE risk, and it originates from cattle which have been subjected to an ante-mortem inspection with favourable results and has not been prepared using the tissues listed in point 2 of Article 2.3.13.10.

Article 2.3.13.16.

Veterinary Administrations of *importing countries* should require:

for tallow derivatives (other than those made from protein-free tallow as defined in Article 2.3.13.6.) intended for food, feed, fertilisers, cosmetics, pharmaceuticals including biologicals, or medical devices

the presentation of an *international veterinary certificate* attesting that:

1) they originate from a BSE negligible risk or BSE minimal risk country or zone;

OR

2) they have been produced by hydrolysis, saponification or transesterification using high temperature and pressure.

Article 2.3.13.17.

Careful selection of source materials is the best way to ensure maximum safety of ingredients or reagents of bovine origin used in the manufacture of medicinal products.

Countries wishing to import bovine materials for such purposes should therefore consider

the following factors:

1) the BSE status of the country and herd(s) where the animals have been kept, as determined under the provisions of Articles 2.3.13.2. to 2.3.13.5.;

2) the age of the donor animals;

3) the tissues required and whether or not they will be pooled samples or derived from a single animal.

Additional factors may be considered in assessing the risk from BSE, including:

4) precautions to avoid contamination during collection of tissues;

5) the process to which the material will be subjected during manufacture;

6) the amount of material to be administered;

7) The route of administration.